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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/257,188	02/25/99	GLENN G	PM244954

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EXAMINER	
EWOLDT,G	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/257,188	Applicant(s) Glenn et al.
	Examiner G. R. Ewoldt	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Jul 20, 2001*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-59* is/are pending in the application.

4a) Of the above, claim(s) *8-20, 22, 38, 44, 46-49, 52-54, 56, 58, and 59* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-7, 21, 23-37, 39-43, 45, 50, 51, 55, and 57* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *6, 7*
18) [ ] Interview Summary (PTO-413) Paper No(s). _____
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other:

DETAILED ACTION

1. Applicant's election with traverse of Group III (claims 1-37, 39-46, 50-51, 55, and 57) and the species:

a) enhancer - alcohol, and

b) adjuvant - *E. coli* heat-labile enterotoxin (LT),

in Paper No. 11 is acknowledged. The traversal is on the grounds that an examination of all types of antigens, i.e., allergen, autoantigen, tumor antigen, and pathogenic antigen would not pose an undue burden. However, as set forth in the restriction requirement, the searches of the different groups comprise different fields of search, thus restriction in proper. Regarding the rejoining of methods of prevention, said methods comprise significantly different fields of search and are thus properly restricted from the elected method.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 38, 47-49, 52-54, 56, and 58-59 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions. Claims 8-20, 22, 44, and 46 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected species of the elected invention.

Claims 1-7, 21, 23-37, 39-43, 45, 50-51, 55, and 57 are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, the sequences on page 50 of the specification must be brought into sequence compliance and identified by SEQ ID NOS:.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 21, 23-37, 39-43, 45, 50-51, 55, and 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,
a method of inducing an immune response, said method comprising pretreating an area of skin an applying an antigen with a cholera toxin (CT) or LT adjuvant,
does not reasonably provide enablement for,
a method of inducing an enhanced therapeutically effective immune response, said method comprising pretreating an area of skin an applying an antigen with an adjuvant.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the breadth of the claims. Regarding the claim of an "enhanced therapeutically effective immune response," the specification discloses 23 examples, some of which demonstrate the induction of an immune response, however, none of the examples demonstrate an immune response that is "therapeutically effective." It is well known in the immunological arts that an immune response can be generated that is not therapeutically effective. See for example Janeway et al. (1994), which teaches that HIV infection induces an immune response, however, said response is not therapeutically effective. See also Feng et al. or Murphy et al.; both references demonstrate that immune responses can be generated that are not therapeutically effective (see particularly Table 1 and Figure 2 respectively). Thus, the demonstration of the induction of an immune response in the instant application is necessary, but not sufficient to support the instant claims drawn to an "enhanced therapeutically effective" immune response. Regarding the breadth of the claims to include any adjuvant, page 27 of the specification discloses that diphtheria toxin (DT) is included as an adjuvant encompassed by the claimed methods. However, Examples 7 and 10 clearly disclose that DT will not function as an adjuvant in the claimed method. In both cases an additional CT adjuvant is required for the induction of an immune response. Thus, the invention as broadly claimed must be considered highly unpredictable. Said invention would require undue experimentation to practice as claimed given Applicant's own disclosure that said invention can not function as claimed.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples encompassing the entirety of the claimed methods, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321c may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-7, 21, 23-37, 39-43, 45, 50-51, 55, and 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 16-24, and 27-35 of copending Application No. 09/266,803 and claims 1-8, 11-23, and 29-30 of copending Application No. 09/316,069. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '803 and '069 applications and the instant application recite methods of transcutaneously inducing an immune response, said methods comprising an antigen and an adjuvant. The difference between the claims of the '803 and '069 applications and the instant application is only the source of the antigens and the addition of an "enhancer" to the instant claims. However, it is the Examiner's position that methods comprising various pathogenic antigens are not patentably distinct and that the use of "enhancers" would be obvious in view of Walker et al. (1996).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. No claim is allowed.

8. Applicant's newly submitted Form 1449, submitted 7/20/01, comprising an IDS of approximately 300 references, has not been initialed because said references have not been provided. While some of the references may have been provided in previous applications, said references are unavailable to the Examiner.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

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October 5, 2001

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